## REMARKS

Applicants add new claim 15 which is a process claim. All product claims have been deleted. The support for new claim 15 is found on page 8, lines 12-15, 37-39, 45 to page 9, line 5. Claims 16-24 are new process claims which cover the features of canceled claims 2-10.

**35 USC § 112, second paragraph**

Claims 1, 11, and 13 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The examiner stated that claim 13 recites the limitation "the second viral coefficient" but there is insufficient antecedent basis for this limitation in the claim. The examiner also stated that claim 14 is provides for the use of a preparation, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

Applicants believe the indefiniteness rejections are moot because claims 13 and 14 have been canceled.

**35 USC § 102(b)**

Claims 1-4 and 8-14 are rejected under 35 USC § 102(b) as being anticipated by Stainmesse et al. (US 5,133,908). Claims 1-6 and 8-14 are rejected under 35 USC § 102(b) as being anticipated by List et al. (US 5,389,382).

The claimed invention relies on a process which is carried out continuously in a mixing chamber in such a way that vigorous mixing of the two components, i.e. the

aqueous solution of the coating material and the ingredient/polymer solution/precipitation takes place. Only if the process is carried out continuously in the mixing chamber the desired product properties, (i.e., uniformity of particle size) can be achieved.

Anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention. *RCA Corp. v. Applied Digital Data Systems, Inc.,* 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984).

Stainmesse et al. and List et al. taken individually do not teach each and every element of the present claims as herein amended.

The process described in US-A 5,133,908, Stainmesse et al., is carried out batchwise on a very small scale (ml, mg), a scale typically used in a laboratory, and either not stirred or only stirred moderately (see col. 4, lines 42 to 44). Stainmesse et. al. do not disclose the spraying of the components in a mixing chamber as a compact jet.

List et al. (US 5,389,382) do not describe that the process needs to be carried out continuously in a mixing chamber. According to the examples, the process is carried out batchwise.

Claims 1-14 are rejected under 35 USC § 103(a) as being unpatentable over List et al. (US 5,389,382) in view of Liversidge et al. (US 5,145,684). The examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of List et al. by substituting casein as taught by Liversidge et al. for gelatin as the coating polymer. However, the

colloidal active ingredient preparations according to the instant invention show distinctly less growth of hydrosol particles than known active ingredient preparations which consist essentially exclusively of active ingredient mass in the core of the colloidal particles.

Regarding the rejection under 35 USC § 103 over List in view of Liversidge, US 5,145,684, applicants point out that the particles disclosed by Liversidge contain of crystalline drug substance and are obtained by a process of wet grinding of a liquid dispersion of the drug substance (see claims 1 and 16). Both the particles and the process taught by Liversidge are different, because the material is crystalline and the process does not include precipitation of the particles. The combination of both teachings cannot lead to the claimed process where the particles contain the active ingredient in amorphous form and the process is carried out continuously. The prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2143.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner, and the rejection under 35 USC § 103 should be withdrawn.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such account.

Respectfully submitted,
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